K083007
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4 510(k) Summary of Safety and Effectiveness

Manufacturer/Distributor/Sponsor	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
510(k) Contact	Sally Foust, RAC Regulatory Affairs Project Manager Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA Telephone: 239/643.5553, ext. 1251 Fax: 239/598.5508 Email: sfoust@arthrex.com
Trade Name	ProWick
Common Name	Wound Dressing
Product Code -Classification Name	FRO Dressing, Wound, Drug
Predicate Device	Arthrex ProWick, K072378
Device Description and Intended Use	The ProWick device is a post-surgical antimicrobial wound dressing containing a variety of elements such as elastic straps, waterproof bandages, dressing, foam islands infused with a silver based antimicrobial agent, and a reusable cold pack, sold sterile. The Arthrex ProWick™ Postoperative Wound Dressing is indicated for the management of post-surgical wounds and the silver component present in the dressing may act as a barrier to colonization of E coli, S aureus, A. niger, C. albicans, and P. aeruginosa within the dressing.
Substantial Equivalence Summary	The ProWick device is substantially equivalent to the predicate ProWick device in which the basic features and intended uses are the same. Any differences between the ProWick device and the predicate ProWick device is considered minor and do not raise questions concerning safety and effectiveness. Based on the information submitted, Arthrex, Inc. has determined that ProWick with two-year shelf-life labeling is substantially equivalent to the currently marketed predicate device.

5 Introduction

This **SPECIAL 510(k)** premarket notification is submitted to obtain clearance for the ProWick device with two-year shelf life labeling. This device is being submitted as a modification to **K072378**, *Arthrex ProWick*. The ProWick device with two-year shelf life labeling requires the submission of a pre-market notification due to this *labeling change*.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 8 2009

Arthrex, Inc.
% Ms. Sally Foust
Regulatory Affairs Project Manager
1370 Creekside Boulevard
Naples, Florida 34108-1945

Re: K083007
Trade/Device Name: ProWick
Regulatory Class: Unclassified
Product Code: FRO
Dated: March 31, 2009
Received: April 3, 2009

Dear Ms. Foust:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3 Indications for Use Form

Indications for Use

510(k) Number: K083007

Device Name: ProWick

The Arthrex ProWick™ Postoperative Wound Dressing is indicated for the management of post-surgical wounds and the sliver component present in the dressing may act as a barrier to colonization of *E. coli, S. aureus, A. niger, C. albicans,* and *P. aeruginosa* within the dressing.

Prescription Use _X_ AND/OR Over-The-Counter Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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David Krause for MKM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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